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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/713,889	11/14/2003	Benjamin Levinson	WELLSP 3.0-003	1106
530	7590	07/26/2005	EXAMINER	
LERNER, DAVID, LITTENBERG, KRUMHOLZ & MENTLIK 600 SOUTH AVENUE WEST WESTFIELD, NJ 07090			FEDOWITZ, MATTHEW L	
			ART UNIT	PAPER NUMBER
			1623	

DATE MAILED: 07/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/713,889

Applicant(s)

LEVINSON ET AL.

Examiner

Matthew L. Fedowitz

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-5,8-31 and 34-37 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5,8-31 and 34-37 is/are rejected.
- 7) ☒ Claim(s) 1 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)     | Paper No(s)/Mail Date. ____   |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____  | 6) <input type="checkbox"/> Other: ____                                     |

### **DETAILED ACTION**

Claims 1-5, 8-31 and 34-37 are pending in this action. Cancellation of claims 6-7 and 32-33 are acknowledged.

#### ***Claim Objections***

Claim 1 is objected to because the amended claim reads "tin a" and should read "a tin." Appropriate correction is required.

#### ***Claim Rejections - 35 USC § 112 Second Paragraph***

A. Applicant's arguments filed May 6, 2005 have been fully considered. However, the applicant's arguments are not persuasive. Claims 1-4, 8-31 and 34-37 remain rejected and claim 5 is rejected secondary to the amendment thereto under 35 USC § 112 Second Paragraph.

The claims are indefinite for the reasons stated within the office action dated March 25, 2005. Specifically, a claim that is directed to a "tin mesoporphyrin complexed with at least one amino acid" does not direct one skilled in the art as to where on the tin mesoporphyrin the amino acid is complexed. Furthermore, the claims will be interpreted broadly for purposes of examination and the amino acid will be construed to be complexed anywhere on the tin mesoporphyrin core absent direction provided in the specification. In this case, it would be impossible to perform a meaningful and successful prior art search, as this class of compounds is very broad and to search all of the compounds of the class with an amino acid complexed at every site on the tin mesoporphyrin core would be impossible.

If the applicant is attempting to draft claims wherein the amino acid is complexed specifically to one site on the tin mesoporphyrin core then the applicant can traverse this rejection by making it clear on the record and in the claims. For instance, if the amino acid is

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only complexed with tin, then the applicant is encouraged to draft the claims so that this is clear because, as the claims are currently written, they are completely unclear.

B. As a result of the applicant's amendment, claims 34 and 35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 34 is drawn to treating a "medical condition". The phrase "medical condition" is indefinite because there are multitudes of medical condition and it is impossible to know which medical condition the applicant is referring to. In addition, since the type of medical condition to be treated is unknown then it is also impossible to know how much of the active agent is used to treat the claimed "medical condition." Claim 35 is also indefinite, as it depends from an indefinite claim.

Still further, claim 34 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted step is the condition to be treated.

#### ***Claim Rejections - 35 USC § 103***

Applicant's arguments filed May 6, 2005 have been fully considered. However, the applicant's arguments are not persuasive in regard to claims 1-10, 22, 32-35 and 37; and are persuasive for claims 11-20. Claims 1-10, 22, 32-35 and 37 remain rejected under 35 USC § 103(a).

In the porphyrin chemical arts, all porphyrins consist of a central core that can be interpreted to be tertrapyrrollic in nature. In light of this, the claimed compounds, compositions and methods read on that which is taught by Robinson. The applicant is encouraged to examine

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Robinson's claim 1 wherein  $R_1$ - $R_{12}$  and M can be selected in a manner to comprise a tin mesoporphyrin; wherein, an amino acid could be complexed at  $R_3$ ,  $R_6$ ,  $R_9$  or  $R_{12}$ .

The applicant can traverse this rejection by providing direction in regard to the 35 USC §112 Second Paragraph rejection above.

### *Conclusion*

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

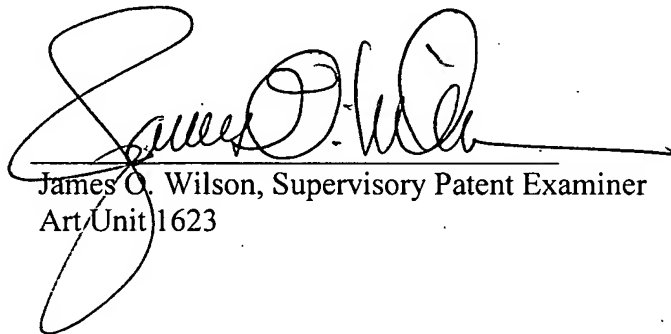
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew L. Fedowitz whose telephone number is (571) 272-3105. If attempts to reach the examiner by telephone are unsuccessful, the examiner's primary, James O. Wilson, can be reached on (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Matthew L. Fedowitz, Pharm.D., Esq.



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James O. Wilson, Supervisory Patent Examiner  
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